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**Odgovornost pri načrtovanju - Smernice za razvoj dolgoročnih strategij (načrtov)
za odgovorno inoviranje**

Responsibility-by-design - Guidelines to develop long-term strategies (roadmaps) to
innovate responsibly

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Responsibility-by-design - Guidelines to develop long-term strategies (roadmaps) to innovate responsibly

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

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Foreword

This CEN Workshop Agreement (CWA 17796:2021) has been developed in accordance with the CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization” and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by a Workshop of representatives of interested parties on 2021-04-21, the constitution of which was supported by CEN following the public call for participation made on 2019-06-27. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

The final text of this CEN Workshop Agreement was provided to CEN for publication on 2021-08-02.

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Introduction

Responsible research and innovation (RRI) addresses the development of products and processes that are safe, ethically acceptable, and responsive to the needs and expectations of people and society.

The essential difference between RRI and existing practices regarding corporate social responsibility (CSR), responsible business conduct, risk, and quality management is RRI's focus on the research and innovation (R&I) process, from the early stages to prototyping to going to market, and the high degree of societal involvement RRI requires to assess potential (future) ethical and social impacts of innovation. The goal of RRI is to design and develop innovations that have socially desirable outcomes, thus addressing specific ethics and social concerns and providing solutions for acknowledged societal challenges (e.g., sustainable development goals). Some examples are provided in the Annex III.

The ability to translate technological developments into innovations that generate benefits and value for the organization and its shareholders and stakeholders and for society is a core aspect of RRI.

Initiatives to put RRI into practice in industry, for instance in the form of action plans, are still limited, with most being related to cooperative projects within EU framework programmes or national equivalents. Examples include Horizon 2020's SwafS (Science with and for Society) projects such as Responsible Industry, Compass, SMART-map, Liv-In, Orbit, Satori, Sherpa, Sienna, and TechEthos.

However, it's worth noting that principles and approaches related to RRI have elements in common with acknowledged business and innovation management methods and practices, such as theory of change, business model generation, stakeholder management, design-thinking, and agile management.¹

The guidelines offered here were developed by the PRISMA project,² which worked with eight industrial pilot projects dealing with the application of transformative technologies in different sectors. The pilots were used to integrate RRI principles in the participating companies' strategies and actions in order to improve the societal value and overall performances of their R&D (research and development) outcomes and to develop specific "pilot RRI roadmaps".

For an effective RRI uptake, it is essential for companies to identify strategies and practices that fit within the realities and constraints in which they operate. The roadmap described in these guidelines aims to help them do just that. The overall goal is to help strengthen aspects of responsibility all along the research, development, and design process for innovations and thus to support a "responsibility-by-design" approach.

Besides helping to identify a vision, a set of actions, and a timeline (roadmap) for implementing RRI approaches, this guideline also analyses the potential barriers, opportunities, and benefits in pursuing RRI.

Within this guidance, we understand research and innovation as intertwined: research (besides its role of creating knowledge) has an applied character and is oriented towards innovation, with the final goal of generating both economic and societal value.

At the industry level, technology roadmapping is already a quite widely utilized method in strategy planning. A technology roadmap visualizes an organization's strategic aims (vision/development plans) and can be utilized to structure its research, development, and business activities. In recent years, the concept of IPRM (innovation policy roadmapping methodology) has been developed to connect the development of technologies and innovations to a wider societal sphere.³ A main aspect of IPRM is identifying those societal needs that create a potential demand for new solutions and possibly favour the emergence of new products and markets.

¹ A description of the relevance of these methods for RRI is provided in Dreyer et al., 2017.

² The PRISMA project received funding from the EU's Horizon 2020 research and innovation programme (grant agreement No. 710059). More information is available on the PRISMA website: www.rri-prisma.eu/

³ Ahlqvist, T., Valovirta, V., & Loikkanen, T. (2012). Innovation policy roadmapping as a systemic instrument for forward-looking policy design. *Science and Public Policy*, 39(2), 178–190

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IPRM integrates a foresight exercise into enabling technologies, applications, products, and markets with analysis of socio-economical and sectorial drivers and policy and regulatory tools and strategies.

The RRI roadmap proposed in this guideline adapts a generic IPRM architecture to the definition of long-term visions and action plans for RRI uptake within the innovation strategies of organizations and others agents (e.g., cooperative projects) active in research and innovation. It provides the methodological and technical conditions to address RRI principles in the context of rapid (and possibly disruptive) scientific and technological developments to ensure such developments are relevant to society.

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1 Scope

This document provides guidelines to develop long-term strategies (roadmaps) for innovating responsibly, thereby helping organizations to achieve socially desirable outcomes from their innovation processes.

These roadmaps encourage a “responsibility-by-design” approach that integrates considerations of technical, ethical, social, environmental, and economic aspects all along the research, development, and design process leading to an innovation.

The document aims at all organizations and agents involved in planning and performing research and innovation and technological development.

The focus is on innovation enabled by transformative technologies.

This document has been designed to be consistent with, and to support, as much as possible, existing management system standards and management/governance standards (e.g. EN ISO 9001). Particular attention has been given to social responsibility (i.e. EN ISO 26000).

2 Normative references⁴

The existing management standards and normative references used in this document are listed below. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 26000, Guidance on social responsibility

ISO 31000, Risk management – Guidelines

ISO 45001, Occupational health and safety management systems – Requirements with guidance for use

EN ISO 14001, Environmental management

EN ISO 9001, Quality management systems – Requirements

Series CEN/TS 16555, Innovation management

Series CWA 17145, Ethics assessment for research and innovation

IWA 26 Using ISO 26000:2010, in management systems

UNI/PdR 27, Guidelines for management and processes development for responsible innovation

UNI/PdR 18, Social responsibility in organizations – Guidance to the application of UNI ISO 26000

⁴ These standards and guidelines (in their scope and contents) refer to and can be used to contribute to the UN’s Sustainable Development Goals. This document also takes into account the Rome Declaration on Responsible Research and Innovation in Europe (European Union, 2014). In addition, it recognizes the need to consider efforts towards responsibility in research and innovation within the broader framework of corporate sustainability, responsible business, and sustainable finance practices (UN Global Compact: unglobalcompact.org), though these aspects are not explicitly addressed within the scope of this guidance.

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EN ISO 56000, Innovation management – Fundamentals and vocabulary

EN ISO 56002, Innovation management – Innovation management system – Guidance

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1**context of the organization**

combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives.

Note 1 to entry: The organization's objectives can be related to its *products* and *services*, investments and behaviour towards its *interested parties*.

Note 2 to entry: The concept of context of the organization is equally applicable to not-for-profit or public service organizations as it is to those seeking profits.

Note 3 to entry: In English, this concept is often referred to by other terms such as "business environment", "organizational environment", or "ecosystem of an organization".

Note 4 to entry: Understanding the *infrastructure* can help to define the context of the organization.

[SOURCE: ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.2**corporate social responsibility (CSR)**

a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis", as well as "the responsibility of enterprises for their impacts on society.

[SOURCE: European Commission, 2011].

3.3**documented information**

information required to be controlled and maintained by an organization and the medium on which it is contained.

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

- the management system, including related processes;
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

3.4

engagement

involvement in, and contribution to, activities to achieve shared objectives.

[SOURCE: ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.5

ethics

systematic reflection on right and wrong conduct according to norms and values that we believe should be followed. Ethics refers to duties, responsibilities, rights, welfare, justice and the avoidance of harms. Typical moral values include autonomy, freedom, dignity, privacy, justice, well-being and responsibility.

[SOURCE: Series CWA 17145]

3.6

framework

an outline, or skeleton, of interlinked items and actions that supports a particular approach to a specific objective and serves as a guide that can be modified as required by adding or deleting items.

3.7

human-centred design (HCD)

characterized by:

- The design is based upon an explicit understanding of users, tasks and environment;
- Users are involved throughout design and development;
- The design is driven and refined by user-centred evaluation;
- The process is iterative;
- The design addresses the whole user experience;
- The design team includes multidisciplinary skills and perspectives.

[SOURCE: ISO 9241-210:2010]

3.8

impact assessment

assessment of research and innovation for its projected or actual societal impacts.

[SOURCE: Series CWA 17145]

3.9

involvement

taking part in an activity, event or situation.

[SOURCE: ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.10

innovation

new or changed *entity*, realizing or redistributing *value*.

Note 1 to entry: Novelty and value are relative to, and determined by the perception of, the *organization* and *interested parties*.

Note 2 to entry: An innovation can be a *product, service, process*, model, method etc.

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Note 3 to entry: Innovation is an outcome. The word “innovation” sometimes refers to activities or processes resulting in, or aiming for, innovation. When “innovation” is used in this sense, it should always be used with some form of qualifier, e.g., “innovation activities”.

Note 4 to entry: For the purpose of statistical measurement, refer to the Oslo Manual (OECD/Eurostat, 2018): New or changed entity’ corresponds to ‘a new or improved product or process, or combination thereof, that differs significantly from the unit’s previous products or processes’. Realising or redistributing value’ corresponds to ‘and that has been made available to potential users or brought into use by the unit’.

[SOURCE: EN ISO 56000]

3.11**innovation ecosystem**

system of organizations, people and resources, complementing each other and contributing to a common objective with regards to innovation.

Note 1 to entry: An innovation ecosystem can include private companies, public authorities, universities, institutes, individual entrepreneurs, investors, researchers as well as funding and infrastructures.

Note 2 to entry: An innovation ecosystem generally includes intangible and qualitative interactions and relationships necessary for its effectiveness.

[SOURCE: EN ISO 56000]

3.12**management system**

set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization’s structure, roles and responsibilities, planning, and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

[SOURCE: ISO/TMB/JTCG Joint technical Coordination Group]

3.13**management standard**

management standard designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse geographical, cultural and social conditions.

[SOURCE: ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2018]

3.14**management system standard (MSS)**

MSS designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse geographical, cultural and social conditions.

[SOURCE: ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2018]

3.15**materiality**

identification and understanding of priorities within the context of social responsibility in which an organization operates. These priorities reflect the economic, social, and environmental factors that need to be considered.

[SOURCE: UNI/PdR 18 Social responsibility in organizations – Guidance to the application of UNI EN ISO 26000]

3.16**monitoring**

determining the status of a system, a process or an activity.

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

[SOURCE: ISO/TMB/JTCG Joint technical Coordination Group]

3.17**organization**

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

[SOURCE: ISO/TMB/JTCG Joint technical Coordination Group]

3.18**participatory design**

a “practice of collective creativity” that emphasizes active involvement by the users and all the stakeholders in design and development of new systems.

[SOURCE: Niemelä et al., 2014].

3.19**process**

set of interrelated or interacting activities which transforms inputs into outputs.

[SOURCE: ISO/TMB/JTCG Joint technical Coordination Group]

3.20**performance**

measurable result.

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, processes, products (including services), systems or organizations.

[SOURCE: ISO/TMB/JTCG Joint technical Coordination Group]

CWA 17796:2021 (E)**3.21****quadruple helix stakeholder**

key local actors from public institutions, private organizations, academia and the public.

[SOURCE: Carayannis et al., 2009]

3.22**quality management**

management with regard to quality.

Note 1 to entry: Quality management can include establishing quality policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement.

[SOURCE: ISO 9000:2015 Quality management systems — Fundamentals and vocabulary]

3.23**responsible research and innovation (RRI)**

transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).

[SOURCE: Von Schomberg, 2012]

3.24**responsible research and innovation (RRI) maturity level**

how RRI is perceived and valued within an organization. Empirical research has identified five different stages: unaware (the organization is not aware of RRI or its components); exploratory/reactive (the organization reacts to external pressures concerning aspects of RRI); defined (the organization has definitions for RRI components and has integrated these components into its practices); proactive (the organization realizes the benefits of RRI and increasingly integrates RRI into its business); strategic (the organization has adopted RRI as a component of its strategic framework and aims to ensure that all R&D activities consider most of the RRI components).

[SOURCE: Stahl et al., 2017]

3.25**roadmap**

strategic plan that defines a goal or desired outcomes and includes the major steps or milestones needed to reach them.

3.26**roadmapping exercise**

collaborative learning process and a tool for drawing up strategies, reaching consensus on requirements and needs, and driving proactive planning and future studies.

3.27**risk**

effect of uncertainty on objectives.

Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats.

Note 2 to entry: Objectives can have different aspects and categories, and can be applied at different levels.

Note 3 to entry: Risk is usually expressed in terms of risk sources, potential events, their consequences and their likelihood.

[SOURCE: ISO 31000:2018 Risk management — Guidelines]

3.28**risk assessment**

overall process of risk identification, risk analysis and risk evaluation.

3.29**risk identification**

process of finding, recognizing and describing risks.

3.30**risk analysis**

process to comprehend the nature of risk and to determine the level of risk.

3.31**risk evaluation**

process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable.

[SOURCE: ISO Guide 73:2009 Risk management – Vocabulary]

3.32**RRI product**

research and innovation output (e.g., product, service, process, model, method) selected by the organization as the focus of the RRI roadmap design.

3.33**social responsibility**

responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behaviour that:

- contributes to sustainable development, including health and the welfare of society;
- takes into account the expectations of stakeholders;
- is in compliance with applicable law and consistent with international norms of behaviour; and
- is integrated throughout the organization and practiced in its relationships.

Note 1 to entry: Activities include products, services and processes.

Note 2 to entry: Relationships refer to an organization's activities within its sphere of influence.

[SOURCE: EN ISO 26000:2020]